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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/19/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/338,729

Applicant(s)

GROSS, DENNIS

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 and 62-84 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 27-30, 34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-26, 31-33, 36-53, 62-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-53 and 62-84 are pending. Claims 1-9, 27-30, 34-35 are withdrawn from consideration, as they are directed to non-elected subject matter. The Amendment filed 10/7/03, Paper No. 28, amended claims 10, 16, 37, 40-41, 44-46, cancelled claims 54-61, and added claims 62-84.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-26, 31-33, 36-53, 62-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of “non-neutralized acid”, “substantially completely absorbed into the skin” and “not thereafter manually removed from the skin” in the instant independent claims, are new and do not find support in the original disclosure. While Applicant has pointed to places in the specification that supposedly support these recitations, the Examiner is unable to find such support. The recitation of viscosity limitations in instant claims 37, 40, 41, 44, 45, 46, 62-74, 83-84, are new and do not find support in the original disclosure. The Applicant directs the Examiner to the Examples in the specification for support of viscosity limitations, but the Examiner is unable to find any viscosity teachings in the Examples.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-26, 31-33, 36-53 and 62-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claims 10, 16, 37, 40-41, 44-46 are vague and indefinite, as they are confusing. These claims recite an acid peel and then recite that the composition is not thereafter manually removed from the skin. The definition of peel, according to Webster's Dictionary, is to strip off an outer layer of ; to remove by stripping. Thus, these recitations seem contrary to one another.

(ii) The term “(about)” in claims 76-78 and 80-82 is vague and indefinite, as the metes and bounds of these claims are unascertainable. The only definition of this term is provided by other composition examples in the specification, wherein “about” ranges can range from 0% to 50%. Thus, it is impossible to ascertain the metes and bounds of the term “(about)”, and hence, the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-15, 24-26, 31, 32, 36, 39, 43, 47, 48, 49, 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis (5,720,949) in view of Hahn et al. (2002/0098210).

The instant invention is directed toward a method for the treatment of skin comprising the sequential steps of applying to the skin a composition comprising an effective amount of an acid suitable as a skin renewing acid in a cosmetically acceptable vehicle, wherein the pH of the composition is between 2.5-4, and allowing the first composition to dry on the skin; and neutralizing said first composition by applying to the skin a second composition comprising an alkaline agent and 0.1-10% of a surfactant/emulsifying agent in a cosmetically acceptable vehicle, wherein the pH is greater than about 7 to 12, and allowing the second composition to dry; wherein the first composition and second composition are both applied by massaging into the skin and are not thereafter removed from the skin, wherein makeup or other cosmetic is optionally applied thereafter to the skin.

Davis teaches a cosmetic mask, wherein a mask is a peel, comprising a first composition and a second composition that are applied sequentially to the face. One of the compositions comprises an acid and the other comprises an effervescent agent (abstract). The effervescent agent is preferably sodium bicarbonate and the acid is an alpha-hydroxy acid such as lactic acid (col. 2, lines 35-38). The acid component makes up about 1-30% of the second composition (col. 3, lines 61-67). Lactic acid has an inherent molecular weight of about 90. The compositions may be applied using a spatula or any other convenient applicator (col. 2, lines 42-47).

The effervescent composition may comprise from about 1-20% of a surfactant system (col. 3, lines 31-33). Surfactants such as cetareths, ceteths, laneths, nonoxynols, octoxynols, glyceryl stearate, PEG-castor oil, poloxamers, poloxamines, and steareths are taught at column 5, line 47-col. 6, line 35. Davis teaches ethoxylated sorbitan esters with fatty acids or alcohols and

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ethoxylated esters having preferably 14-18 carbon atoms, which encompass polysorbate 20 (col. 5, line 60-col. 6, line 4).

The pH of the effervescent composition is from about 7.5 to about 9, preferably between 7.8 and 8.3(col. 7, lines 58-60). The pH of the acid composition is from about 3.5 to about 6 (col. 8, lines 50-64). As a further note, pH is an inherent property of an acid or alkaline agent. Therefore, the pH of a composition comprising an acid or an alkaline agent is inherently either acidic or basic, respectively, unless specifically altered.

For additional suitable acids, see col. 9, lines 8-13. See Example 1 at col. 12 for one composition comprising 5wt.% sodium bicarbonate, 1.5% glyceryl stearate, 5% cetyl alcohol, 1.5% PEG-100 stearate and 1.5% PEG-40 castor oil with a pH of 8.0 and another composition comprising 9.1% lactic acid with a pH of 4.9. The reference teaches at column 13, lines 7-9, that the composition bubbles because of the reaction between the effervescent agent and the acid. This is interpreted as meaning that the alkaline, effervescent agent neutralizes the acid component.

Davis teaches the compositions as being massaged into the skin. At col. 10, lines 58-60, it is disclosed that the cream mask composition (1st composition) is allowed to remain on the face for up to about 10 minutes. At col. 11, line 66-col. 12, line 2, it is disclosed that the second composition is left on the skin for up to about 30 minutes after which time the composition can be scraped from the skin. Thus, the compositions are given time to dry once they are applied to the skin.

The reference does not teach applying the neutralizing composition to the acid composition. However, it is respectfully pointed out that no criticality is seen in the particular

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order of application. Since the compositions are used in conjunction with one another, the ultimate effect to the skin is the same. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the alkaline solution to the acid solution because of the expectation of achieving similar cosmetic effects.

Regarding the limitation “and are not thereafter removed from the skin” in the instant independent claims, it is respectfully pointed out that giving the broadest interpretation of this language, Davis meets this limitation. The Examiner respectfully points out that Davis teaches that his compositions are allowed to remain on the face for up to about 30 minutes. Thus, the compositions are not removed from the skin for at least 30 minutes. Since the instant specification does not define the time period referred to by this phrase and since all cosmetic compositions must ultimately be removed from the skin, the teachings of Davis meet this limitation.

Davis teaches the alkaline composition in the form of a cream and the acid composition in the form of a gel. The references an explicit teaching of liquid forms of the compositions.

Hahn et al. teach cosmetic compositions for application to the skin. Liquid, gel and creams are taught as interchangeable cosmetic formulations. See title, abstract; Claims 1 and 45.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the compositions of the combined references in the form of a liquid because Hahn et al. teach liquid, gel and creams as interchangeable cosmetic composition forms. It is additionally pointed out that given the broadest reasonable interpretation of the claims, wherein a liquid is defined as being neither a gas or a solid, the compositions of Davis are liquids.

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The prior art and the instant invention teach the same method of applying the same composition. Regarding the property limitations in the instant claims, it is respectfully pointed out that the composition of the prior art containing the same components as instantly claimed must exhibit the same properties, as a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

It is respectfully pointed out that for the purposes of searching for an applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to comprising. If an applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of", applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. See MPEP 2111.03.

Claims 16-21, 51, 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis in view of Hahn et al. as applied to claims 10-15, 24-26, 31, 32, 36, 39, 43, 47, 48, 49, 50above, and further in view of Kunz et al. (6,171,347).

Davis and Hahn et al. are applied as discussed above. The references lack kits.

Kunz et al. teach a multi-compartment kit comprising a first and second composition with a pH of 1,8-6, which overlaps the instantly claimed pH ranges of the acidic composition. The second composition comprises an acid such as alpha-hydroxycarboxylic acids. See claim 18. See Examples 1.1-1.5 bridging cols. 11-12 for a composition comprising sodium hydroxide,

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sodium lauryl ether sulfate and ammonia, and stripper gel compositions comprising ascorbic acid, inter alia. An applicator is taught at col. 11, lines 64-65. The pH value of the first composition is preferably from 5-9 (col. 9, lines 7-8). This either overlaps or encompasses the instantly claimed pH ranges of the alkaline composition. At col. 9, lines 14-16 it is taught that buffers such as alkali carbonates can be added to the composition. For surfactant/emulsifiers, see col. 8, lines 52-57.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the compositions of Davis in the kit of Kunz et al. because of the expectation of achieving ease of application by providing a single carrier for two compositions that must be sequentially applied.

Claims 33, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis in view of Hahn et al. as applied to claims 10-15, 24-26, 31, 32, 36, 39, 43, 47, 48, 49, 50 above, and further in view of Smith et al (5,242,433).

Davis and Hahn et al. are applied as discussed above. The reference lacks pads.

Smith et al. teach a packaging system of applicator pads for topical drug delivery and a method of applying tow dermatological agents to the skin sequentially using the applicator pads (title and abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the compositions of Davis as being applied by a pad, as taught by Smith et al., because Davis teaches that the compositions can be applied to the skin via a spatula or other means and because of the expectation of achieving an applicator that is flexible and conforms to the contours of the face, allowing for easier application of the compositions.

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Claims 42, 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis in view of Hahn et al. and further in view of Kunz et al. as applied to claims 10-21, 24-26, 31, 32, 36, 39, 43, 47, 48, 49, 50, 51 and 53 above, and further in view of Smith et al. (5,242,433).

Davis, Hahn, and Kunz et al. are applied as discussed above. The references lack pads.

Smith et al. teach a packaging system of applicator pads for topical drug delivery and a method of applying tow dermatological agents to the skin sequentially using the applicator pads (title and abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the compositions of Davis as being applied by a pad, as taught by Smith et al., because the combined references teach that the compositions can be applied to the skin via a spatula or other means and because of the expectation of achieving an applicator that is flexible and conforms to the contours of the face, allowing for easier application of the compositions.

Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis in view of Hahn et al. and further in view of Kunz et al. as applied to claims 10-21, 24-26, 31, 32, 36, 39, 43, 47, 48, 49, 50, 51 and 53 above, and further in view of Linn et al. (4,797,273) and STN Registry Print-out.

Davis, Hahn et al. and Kunz et al. are applied as discussed above. The references lack octoxynol-9 and polysorbate 20.

Linn et al. teach skin moisturizing microemulsions. Sorbates, such as polysorbate 21 and octoxynol-9 are taught as cosmetically acceptable surfactants. See Col. 6, lines 14-33.

As taught by the REGISTRY file printout for polysorbate-20 obtained on STN, polysorbate-20 and polysorbate-21 are considered equivalent compounds.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach polysorbate-20 and/or octoxynol-9 as the surfactant(s) in the alkaline composition of the combined references because of the expectation of achieving similar surfactant effects with surfactants that are cosmetically acceptable. Furthermore, it is respectfully pointed out that Davis teaches polysorbates and octoxynol as surfactants, and it is within the skill in the art to substitute one known species of surfactant for another.

Response to Arguments

Applicant argues, "This product must be applied to the skin using a spatula or other similar means and does not flow appreciably when applied to the skin". This argument is not persuasive. The Examiner respectfully points out that in Col. 2, Davis teaches "The cosmetic mask product is used by first applying a uniform layer of the first or second composition to the skin of the consumer using a spatula or other means. Thereafter, the other composition is applied to the skin of the consumer in any convenient way, and is massaged into the skin with consequential admixing. Thus, massaging the compositions into the skin is taught. Additionally, it is respectfully pointed out that a spatula can be utilized to massage a composition into the skin, as the spatula is relied upon to carry the composition, wherein the consumer then spreads the composition on the spatula onto the skin, thus massaging the composition into the skin. The Examiner additionally respectfully points out that Webster's Dictionary defines a liquid as having the properties of a liquid : being neither solid nor gaseous. Thus, Davis teaches liquids.

Applicant argues, "The mask of Davis results in a thick layer on the skin, which subsequently is manually removed from the skin by means of a cloth or scraper, especially to abrade the skin to remove dirt, dead skin and oil". This argument is not persuasive. The

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Examiner respectfully points out that Applicant is basing this argument on a recitation in the claim that is rejected as new matter.

Applicant argues, "Applicant respectfully asserts that Hahn does not teach that all compositions are interchangeable, but rather that its particular calcium cation may be incorporated into various topical vehicles". This argument is not persuasive. It is respectfully pointed out that Hahn is relied upon as a general teachings that discloses that it is known in the art to interchange liquid and gel formulations for cosmetic compositions that are applied to the skin.

Applicant argues, "Kunz does not teach nor suggest Applicant's first and second sequentially applied compositions, which are dermatological". This argument is not persuasive, as Kunz is merely relied upon to teach that kits for cosmetic products that contain more than one composition that are to be applied separately, are known and conventional in the art.

Response to Applicant's 132 Declaration

The Examiner respectfully directs Applicant to the guidelines for showing unexpected results. It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

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In the instant case, Applicant has provided no factual data and no comparison of the closest prior art (Davis) with that of the instant invention. The instant declaration merely recites one person's perspective without data to substantiate his statements.

The Declaration states, "All of the combined benefits of the presently claimed method would not have been achieved if the sequential order of application of the claimed first composition to the claimed second composition was reversed because the skin would then never be exposed to the non-neutralized acid in its non-conjugated stronger form. For example, the acids employed in the first composition are significantly effective in exerting their dermatological benefit when applied to the skin in their non-neutralized form and maintained in this form for a period of time on skin". This argument is not persuasive, as the declaration provides no data showing the criticality of the sequential order of application and how this unexpectedly compares to the closest prior art (Davis).

The Declaration states, "The initial exposure of the skin to the first composition including its non-neutralized stronger acid, followed by neutralization with the second composition is a necessary sequential step in the claimed process for the desired mechanism of action and advantageous results achieved by the invention". Again, this argument is not persuasive, as the declaration provides no data showing the criticality of the sequential order of application and how this unexpectedly compares to the closest prior art (Davis).

The Declaration states, "as a result of a rapid change in pH when the composition of Step 1 is neutralized by the composition of Step 2, there is an increase in vasopermeability causing slight edema in the skin, which helps reduce the appearance of lines and gives the skin a healthy appearance. . . Advantageously, the neutralization step potentiates the anti-aging and anti-acne

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effects". This argument is not persuasive. Again, Applicant has provided no data or comparative results, or shown anything unexpected about the instant invention. Second, it is respectfully pointed out that Davis teaches a method that results in a rapid pH change and teaches neutralization. Thus, it appears that the method of Davis would achieve these same results.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30), with alternate Mondays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER
11/14/03